IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC., Plaintiff v. CEPHALON, INC., et al. Defendants	CIVIL ACTION No. 2:06-cv-2768 **ORAL ARGUMENT REQUESTED**

DEFENDANT CEPHALON, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION *IN LIMINE* TO PRECLUDE APOTEX INC. FROM OFFERING EVIDENCE OR ARGUMENT RELATING TO ALLEGED PRIOR ART "REFERENCES" NOT TIMELY DISCLOSED IN ITS INVALIDITY CONTENTIONS

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Cephalon, Inc. ("Cephalon") respectfully submits this motion *in limine* to preclude Apotex Inc. ("Apotex") from offering argument and evidence on the subject of patent invalidity that Apotex failed to timely disclose during the discovery period.

Specifically, Apotex (through its experts) apparently seeks to make the new argument at trial that the patent-in-suit – U.S. Patent No. RE37'516 ("'516 Patent") – is invalid under 35 U.S.C. §103 based on twelve alleged prior art "references" – patents, publications and documents – that Apotex failed to disclose to Cephalon during fact discovery, in violation of this Court's order and federal disclosure requirements. *See* Feb. 19, 2010 Scheduling Order ¶ 4 (Dkt. 203); Fed. R. Civ. Pro. 26(e)(1). The Court should preclude Apotex from using references that were not timely disclosed. Furthermore, Apotex should be limited to making its obviousness case based on the seven prior art references specifically discussed in the "Preliminary Claim Chart" Apotex provided in its Invalidity Contentions.

Background

On April 16, 2010, Apotex served its Initial Invalidity Contentions ("Contentions"), containing a list of seventy-four alleged prior art references. (Ex. 1[1], Contentions at 3 and Exhibit A).[2] Apotex also provided a "Preliminary Claim Chart" ("Chart") with its Contentions purporting to explain "how each ['516 Patent] claim asserted by Cephalon is invalid for either anticipation or obviousness, on an element-by-element basis." (Ex. 1, Contentions, at 11.) The Chart contains an element-by-element discussion of seven prior art references and how they

[1] Unless otherwise noted, all exhibits referenced herein are attached to the Declaration of Sadaf R. Abdullah In Support of Defendant Cephalon, Inc.'s Motion *In Limine* To Preclude Apotex Inc. From Offering Evidence or Argument Relating To Alleged Prior Art "References" Not Timely Disclosed In Its Invalidity Contentions.

[2] Although Apotex now contends that the '516 Patent is invalid for failing to satisfy the "written description" and enablement requirements of 35 U.S.C. §112 ¶ 6, it made no such allegation in its Contentions.

allegedly invalidate the asserted claims of the '516 Patent. Contentions at Exhibit C. No such discussion was provided for the other sixty-seven references.

On June 25, 2010, Cephalon served interrogatories asking Apotex to more specifically explain its invalidity arguments, and in particular to identify the references and the reasoning behind its "obviousness" contention with particularity. (*See* Ex. 2, Cephalon's Second Set of Interrogatories to Apotex, No. 23.)

On July 26, 2010, Apotex responded by "refer[ring] Cephalon to Apotex's Preliminary Invalidity Contentions…" and provided no other substantive response.

On August 13, 2010, the date on which fact discovery closed, Apotex supplemented its response to Interrogatory No. 23 by providing a disclosure substantially identical to its Chart, with no new additional references.[3] Apotex also cited the same seventy-four references disclosed earlier in its Contentions, but with no additional discussion. (*See* Ex. 3, Plaintiff Apotex Inc.'s First Supplemental Responses to Defendants Cephalon, Inc.'s Second Set of Interrogatories (Nos. 16-24) at 47-51.)

On October 29, 2010, more than six months after serving its Contentions and Chart, and months after fact discovery closed, Apotex submitted expert reports, including two reports from Drs. David Feifel and Anthony Palmieri III. In these reports, Apotex's experts relied on some of the prior art references that had been previously identified by Apotex in its Contentions, but also discussed twelve additional references that Apotex had never disclosed before in its Contentions and interrogatory responses. Furthermore, Dr. Palmieri, Apotex's primary expert on the issue of

[3] The amended version of the Chart submitted on August 13, 2010 also included citations to "Lafon manufactured modafinil tablets and documents sent to Cephalon from Lafon characterizing the modafinil and tablets," but did not identify specific Lafon documents on which Apotex intended to rely. (*See* Ex. 3, Plaintiff Apotex Inc.'s First Supplemental Responses to Defendants Cephalon, Inc.'s Second Set of Interrogatories (Nos. 16-24) at 39.)

obviousness, cited to a total of thirty-seven references in his report, far more than the seven that were previously discussed in Apotex's Chart.[4]

Argument

Rule 26(e)(1) of the Federal Rules of Civil Procedure states that a litigant must "supplement or correct its [interrogatory] disclosure or response …in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during … discovery…." Under Fed. R. Civ. P. 37(c)(1), the penalty for failure to meet this obligation is clearly defined: "If a party fails to provide information …as required by Rule 26(a) or (e), the party is not allowed to use that information …at a trial, unless the failure was substantially justified or is harmless."

Courts regularly rely on these rules to preclude parties from presenting arguments or evidence that were not properly and timely disclosed in discovery. *See, Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 851 (Fed. Cir. 2006) (affirming exclusion of prior art first identified after the close of discovery to avoid unfair and prejudicial surprise and stating "the purpose of discovery is to enable the parties to obtain the factual information needed to prepare their cases for trial"); *Transclean Corp. v. Bridgewood Servs*., 290 F.3d 1364, 1373-74 (Fed. Cir. 2002) (upholding district court's ruling precluding defendant from contesting infringement where it had failed to answer plaintiff's contention interrogatory regarding infringement); *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 550-51 (Fed. Cir. 1998) (affirming district court's exclusion of prior art reference despite defendant's compliance with 35 U.S.C. § 282 requirement of notice

[4] In addition, on February 25, 2011, Apotex served a "282 Notice" stating that it intended to use as many as sixty-eight prior art references at the upcoming trial. (*See* Ex. 4, Plaintiff Apotex Inc.'s Notice Pursuant to 35 U.S.C. § 282 at 3-8.)

to plaintiff at least thirty days prior to trial based on defendant's failure to disclose prior art in response to plaintiff's interrogatories); *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, No. CIVA 05-132 JJF, 2007 WL 521894, at *4 (D.Del 2007) (excluding defendant's untimely disclosed references from trial); *Velez v. QVC, Inc.*, No. Civ.A. 00-5582, 2004 WL 1175726, at *1 (E.D.Pa. 2004) (precluding certain evidence that was not timely disclosed under Rule 26); *In re Safeguard Scientifics*, No. Civ.A. 01-3208, 2004 WL 2644393, at *5 (E.D.Pa. 2004) ("*Safeguard II")* (precluding evidence under Rule 37(c)(1) and rejecting defendants' proposed re-deposition as a cure for prejudice because "'nearly three years have elapsed since [the case's] inception, discovery has closed and the matter is now trial-ready.'" (citing *In re Safeguard Scientifics*, 220 F.R.D. 43, 49 (E.D.Pa. 2004) ("*Safeguard I")*).

The twelve untimely-disclosed references should be precluded. Apotex's disclosure of twelve additional prior art references in expert reports served in October 2010 was untimely by at least six months. These references should have been disclosed in its Contentions served in April 2010 and certainly before the close of fact discovery in August 2010. Apotex had ample time to prepare its Contentions and Chart, and to amend those disclosures and timely supplement its interrogatory responses. It chose not to do so.[5] Apotex has provided no justification for why it did not comply with this Court's Scheduling Order or the Rule 26 disclosure requirements. *See Safeguard II* at *5 (finding preclusion of evidence warranted when plaintiffs offered "no justification" for delay in their disclosure of evidence.) The twelve alleged prior art references which were not timely-disclosed should be precluded.

[5] By contrast, when Cephalon finished testing Apotex's Canadian products, it supplemented its Infringement Contentions within a few days. (*See* Defendant Cephalon, Inc.'s Supplemental Infringement Contentions, Oct. 25, 2010, Dkt. No. 339.)

Apotex should be required to limit its obviousness case to the seven references specifically discussed in its Chart. In addition to the preclusion of untimely references, and for the purposes of making trial more manageable, Apotex should be required to base it obviousness case solely on the seven alleged prior art references specifically discussed in its Chart.

The Court's Scheduling Order required that Apotex submit such a Chart "showing for each claim asserted by Cephalon, on an element-by-element bases, Apotex's contentions on how the patents-in-suit are invalid for either anticipation or obviousness." Cephalon's Interrogatory No. 23 also specifically requested disclosure of "every prior art reference or *combination of prior art references* that you contend renders the claimed invention(s) obvious," and "[f]or each such combination of prior art references," a description of "all evidence that you contend shows a motivation to combine the prior art references, including a specific identification of any knowledge in the art or problem to be solved pertinent to motivation" (emphasis added).

The Chart is the only document timely served by Apotex in which Apotex purports to state, on an element-by-element basis, how any prior art reference (or combination of prior art references) allegedly invalidates any asserted claim of the '516 Patent.[6] Indeed, Apotex contended that the seven references discussed in the Chart alone were sufficient to meet Apotex's burden of proof on obviousness. To make trial efficient, Apotex should not be permitted to clutter the record with dozens of superfluous prior art references, twelve of which were untimely disclosed.

Conclusion

For the foregoing reasons, Cephalon respectfully requests that the Court enter an order: (1) precluding Apotex from introducing references that it failed to disclose in its Invalidity

[6] A similar chart was appended to Dr. Palmieri's initial report, but it discusses four references that were not timely disclosed. (*See* Ex. 5, Expert Report of Anthony Palmieri, III Ph.D., Oct. 29, 2010 at Exhibit C.)

Contentions; and (2) requiring Apotex to make its obviousness case based solely on the references specifically discussed in the "Preliminary Claim Chart" Apotex provided in its Invalidity Contentions.

March 7, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on the date set forth below the foregoing Defendant Cephalon, Inc.'s Motion *In Limine* To Preclude Apotex, Inc. From Offering Evidence Or Argument Relating To Alleged Prior Art "References" Not Timely Disclosed In Its Invalidity Contentions, Memorandum in Support, Declaration of Sadaf R. Abdullah and Exhibits in Support, and proposed Order were electronically filed pursuant to the Court's CM/ECF system, and that those documents are available for downloading and viewing from the CM/ECF system. Notice of this filing will be sent to all counsel of record by operation of the CM/ECF system.

/s/ Robert J. Gunther, Jr.
Robert J. Gunther, Jr.

Date: March 7, 2011